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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/481,990 01/11/00 LESAGE

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EXAMINER

TEDESCCHI, B  
ART UNIT PAPER NUMBER

1642  
DATE MAILED:

03/20/01

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/481,990	LESAGE ET AL.
	Examiner Bruc W. Tedeschi	Art Unit 1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 and 14-26 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 11-13 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 18) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other:

### **DETAILED ACTION**

This application was filed January 11, 2000 and is a divisional of US Patent# 6,013,470 filed on November 15, 1996 and issued on January 11, 2000. Priority is claimed, under 35USC § 119, to foreign application #96/01565 filed on February 8, 1996. A preliminary amendment was received on January 11, 2000 in which claims 49-53 and 58-67 were cancelled and new claims 15-26 entered. Claims 1-26 are pending.

#### ***Election/Restrictions***

Applicant's election with traverse of Group II, claims 11-13 in Paper No. 5 is acknowledged. The traversal is on the ground that the burden of demonstrating that Groups II and III are patentably distinct has not been met because the use of a protein as immunogen to make an antibody does not constitute a specific, substantial, and credible utility so as to meet the requirements of 35USC § 101.

This is not found persuasive because the use of protein as immunogen was given as only one, of many, examples in which the specific product in Group II could be used in a process materially different from Group III. The requirement is still deemed proper and is therefore made FINAL.

Claims 1-10 and 14-26 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 11-13 are under consideration.

#### ***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in France on February 8, 1996. It is noted, however, that applicant has not filed a certified copy of the foreign application as required by 35 USC § 119(b).

***Specification***

The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

**Arrangement of the Specification**

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
  - 1. Field of the Invention.
  - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (i) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing (see 37 CFR 1.821-1.825).

The specification is objected to because there is no subsection entitled "Brief Description of the Drawings".

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitations of "properties and structure of a TWIK-1 type channel" are vague and indefinite because the metes and bounds of the encompassed channels cannot be determined. The specification does not provide clear and specific guidance regarding what is considered to be included as a "property" of TWIK-1 and what is to be expressly excluded as a "property" of TWIK-1. Likewise, the specification does not provide clear and specific guidance regarding what structures are included as a structure of TWIK-1 and what structures are to be included. Finally, it is not clear what constitutes a "TWIK-1 type" channel. There is no guidance regarding what constitutes a "type" channel and what is excluded such that one of skill in the art would be apprised of the metes and bounds of the claimed polypeptide.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11-13 are rejected under 35 U.S.C. 101 because the claimed invention lacks a credible, substantial, specific, or well-established utility.

Claims 11-13 are drawn to purified potassium channels and a pharmaceutical composition comprising potassium channels that display, *inter alia*, a two-pore domain structure with inward rectifying properties. The claimed channels are not supported by either a specific and substantial asserted utility or a well-established utility. Applicant only states in the specification that purified channel proteins provide new means for prevention, treatment, or diagnosis of diseases (page 3, lines 9-12 and page 16, lines 1-3). However, applicant does not provide: (1) evidence for a specific disease or syndrome wherein a potassium channel would have utility or (2) evidence of a specific disease wherein a two-pore, inward rectifying potassium channel would have more utility than other types of potassium channels. Clearly further research would be required to identify a disease in which a two-pore domain, inward-rectifying channel protein would be useful. Therefore, the channel proteins drawn by claims 11-13 are not sufficient to identify or confirm a "real world" context of use. See *Brenner v. Manson*, 383 U.S. 519, 535-6, 148 USPQ 689, 696 (1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." A patent, therefore, is not a license to experiment. See also the Revised Interim Utility Guidelines available at [www.uspto.gov](http://www.uspto.gov).

Claims 11-13 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

If the protein of claims 11-13 were found to have a patentable utility, the invention of claim 13 would still not satisfy the criteria under 35 U.S.C. 112, first paragraph.

Many factors are considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue”. These factors include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction or guidance provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Claim 13 is drawn to a pharmaceutical composition for the compensation of a deficiency in the potassium channels at the level of one or more tissues.

Claim 13 is not enabling for the following reasons: (1) the specification and the prior art provide no working examples that teach a protein-based pharmaceutical composition for the treatment of membrane channel deficiency; (2) the specification provides no direction to enable the invention; and (3) the level of predictability is low. Predictability is low because treatment of disease with protein-based compositions is subject to multi-factorial problems, given the current state of the art. For example, Sternson (New York Academy of Sciences, 207:19-21, especially page 19, paragraph 3) teaches that there are significant obstacles to protein delivery by any route of administration and these obstacles include chemical/physical instability, enzymatic

breakdown, potential for eliciting an immunogenic response, and inefficient transport suitable to support therapeutic needs.

In the absence of further guidance from the applicants as to how a pharmaceutical composition of a TWIK-1 protein could be reasonably used to replace a potassium channel deficiency *in vivo* and in view of the unpredictability of therapies based on proteinaceous pharmaceutical compositions, one skilled in the art would be forced into undue experimentation to practice the invention as claimed.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11 and 12 are rejected under 35 U.S.C. 102(a) as being anticipated by Ketchum et al. (Nature 376:690-6, 1995).

Claims 11 and 12 are drawn to a protein comprised of a sequence for functioning as a potassium channel and displaying properties of a TWIK-1-like potassium channel, whereby one of those properties is a structure with two pore domains.

Ketchum et al. teach a protein that has a sequence for functioning as a potassium channel and the sequence contains two pore domains (Page 690, paragraph

1). Since all the limitations of the claims are anticipated by Ketchum et al., the claims are rejected.

Claims 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Lu and MacKinnon (Nature, 1984, 371:243-245).

Claims 11 and 12 are drawn to a protein comprised of a sequence for functioning as a potassium channel and displaying properties of a TWIK-1-like potassium channel, whereby one of those properties is inward rectification.

Lu and MacKinnon teach a protein that has a sequence for functioning as a potassium channel and the channel displays inward-rectifier properties (Page 243, 1<sup>st</sup> column, 1<sup>st</sup> paragraph). Since all the limitations of the claims are anticipated by Ketchum et al., the claims are rejected.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce W. Tedeschi whose telephone number is 703-306-4823. The examiner can normally be reached on Monday - Friday, 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-3014 for regular communications and 703-308-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Bruce W. Tedeschi, PhD  
March 13, 2001



YVONNE EYER, PH.D  
SUPERVISORY PATENT EXAMINER  
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